

# Preserve the Value of Yesterday's Study Data in Today's World of eSubmissions

As regulatory agencies around the world rapidly adopt Clinical Data Interchange Standards Consortium (CDISC)-standardized data for submissions, you are likely facing the challenge of how to work with legacy databases. Quintiles Biostatistics can successfully convert data that are inconsistent in structure and content — even data sourced from multiple sponsors and vendors — to create fully consistent databases that adhere to Study Data Tabulation Model (SDTM) specifications.

By working with Quintiles on this complicated and daunting task, you can avoid what is potentially a critical rate-limiting step for the successful completion of your submission. We provide formal CDISC SDTM Theory and Application training for all of our Biostatistics staff — and with more than 320 employees with CDISC expertise, located in 14 offices worldwide, Quintiles has the dedicated resources to handle any size CDISC conversion in a timely and cost-efficient manner.

## A RECENT CASE STUDY

Quintiles Biostatistics worked closely with three co-sponsors to convert data from more than 30 studies into CDISC-standard formats in support of an eNDA application. The studies were conducted over a period of more than 10 years, and there was wide variation in the data collection standards. We developed a data standardization plan specifying which SDTM domains would be created, and imputation and formatting rules to be applied. Included in our efforts were substantial FDA interactions. Submission of these CDISC-compliant data files resulted in the FDA's acceptance of the entire CDISC database for all legacy studies without any requests for changes or further information.



## Experience in Database Conversion

Through the successful completion of numerous submissions for a variety of sponsors, Quintiles Biostatistics has gained the experience and knowledge required to convert databases to CDISC SDTM format. We have a solid understanding of the expectations of regulatory agencies with respect to submission of data and all associated documentation.

## Consistency and Accuracy

We can develop a complete strategy for the conversion process by drilling down to the details of each database. Our programming expertise allows us to apply an efficient and systematic process to ensure consistency and accuracy of the final product.

## In-Depth Understanding of CDISC

Quintiles has provided leadership in the development of the CDISC standards — including being the first global provider of the full range of drug development and marketing services to be certified as a CDISC Registered Solutions Provider. Our involvement provides us a unique and beneficial perspective to assist sponsors in compiling CDISC-compliant deliverables.

## Flexible Solutions

We collaborate with our customers to get results. Quintiles can provide either a standard CDISC solution or our staff can work with you to tailor a solution to meet your needs.

### CONSIDER THESE LEGACY DATABASE ISSUES:

- > What study data are required for the submission [CRF vs analysis] and in what format?
- > The timing of the study database conversion. This work can be done as studies are completed and can be independent of other submission work.
- > What will be the basis of the integration process — the CDISC converted data or the original data?
- > Which version of CDISC SDTM requirements will you follow? It is expected that the CDISC SDTM Version 3.1.2 will be available during 2009.

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